PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Barcelon, et al.	Examiner: Wong, Leslie
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For: ENHANCED FLAVORING COMPOSITIONS CONTAINING N-ETHYL-P-MENTHANE-3-CARBOXAMIDE	Dated: December 23, 2008
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Commissioner for Patents
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DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I, Maura Titone hereby declare and state as follows:

1. I am a Sensory Panel Leader, and have been working at the Cadbury Science & Technology Center for 11 years. This declaration is submitted in support of the patentability of the claimed invention.
2. In my role as Sensory Panel Leader, I have conducted tests and analyses on various proposed consumer products. I routinely conduct descriptive analysis testing using the Spectrum™ method. This methodology involves a panel consisting of highly trained individuals who are asked to taste various products and measure the intensity of various product attributes. Product perception, commonly described by consumers as product "flavor" or product "taste" includes aromatic attributes, taste attributes, and feeling factors. Aromatic attributes are

experienced retronasally and include notes such as fruit, mint, spice, and the like. Taste attributes include sweet, salt, sour, bitter, and umami while feeling factors include cooling, warming, and tingling. Depending on the objective of the testing, the panel provides intensity ratings on these various attributes. The data generated by the panel is statistically analyzed. Using the statistical analysis and trends observed during the testing, sensory scientists can make recommendations regarding consumers' likely reactions to the product, such as the likelihood that consumers will detect an enhanced flavor perception.

3. Such panel evaluations are generally accepted and widely used in the industry as providing accurate and reliable data, which may be used to evaluate the potential consumer response to various products.

4. I have been informed that the invention as currently claimed in this application includes a chewing gum composition which includes an effective amount of an enhanced flavoring composition. The enhanced flavoring composition includes (1) a fruit flavoring agent present in an amount of from about 97.8 to about 99.96% of the enhanced flavoring composition and (2) an amount of N-ethyl-p-menthane-3-carboxamide (also referred to as "WS-3") in an amount effective to enhance the flavoring agent, and particularly in an amount of from about 0.04 to about 2.2% by weight of the enhanced flavoring composition. The enhanced flavoring composition is present in an amount of from about 0.8 to about 3.5% by weight of the chewing gum. Thus, WS-3 is present in an amount of from 0.00032 to about 0.077% by weight of the chewing gum.

COMPARATIVE TESTS

5. I was asked to conduct a series of tests to investigate the benefit of adding WS-3 to fruit flavors in chewing gum. In particular, I was asked to evaluate whether there is a difference in fruit taste perceptions between gums with and without WS-3. Further, I was asked to evaluate the fruit taste perceptions in chewing gums which included reduced-menthol mint, in addition to fruit and WS-3.

The Spectrum™ Method of Descriptive Analysis

6. Flavor and texture attributes of products can be reliably and reproducibly measured using sensory analysis methods known as descriptive analysis techniques. The Spectrum™ method of descriptive analysis is described in MORTEN MEILGAARD, D.SC. ET AL., SENSORY EVALUATION TECHNIQUES (3d ed. 1999). The Spectrum™ method is a custom design approach meaning that the highly trained panelists who generate the data also develop the terminology to measure the attributes of interest.
7. The Spectrum™ method uses intensity scales created to capture the intensity differences being investigated. These intensity scales are anchored to a set of well-chosen references. Using these references helps make the data universally understandable and reproducible over time. This ability to reproduce the results at another time and with another panel makes the data potentially more valuable than analytical techniques which offer similar reproducibility but lack the ability to fully capture the integrated sensory experiences as perceived by humans.
8. Sensory methods such as descriptive analysis can be conducted on a screening basis or on a full panel basis. When testing is done on a screening basis, there may be fewer panelists and

those panelists may use an abbreviated scale such as a 5 point scale for rating the products. In this case, panelists typically rate the product attributes once (one replication). A screening basis may be used when time and/or amount of product for generating the data is limited and/or when data from an abbreviated scale will adequately distinguish the samples. When testing is done on a full panel basis, more panelists may be involved and a complete scale, such as a 15 point scale, may be used. In this case, two replications are typically conducted with the full panel. When choosing whether to use a screening or full panel basis for the testing, sensory scientists consider a range of variables such as cost, time, objective, number of samples, etc.

9. Tests conducted on a screening basis or on a full panel basis are generally considered acceptable methods in the consumer science community. The results are indicative of the sensations of flavor, taste, or any other attributes desired of the product tested.

10. I was asked to conduct an evaluation of chewing gum products incorporating WS-3. In particular, I was asked to conduct an evaluation of chewing gum products containing WS-3 in combination with other flavors and components. I conducted two phases of tests (Phase I and II) to fully evaluate various attributes of the chewing gum compositions. Phase I included a series of six chewing gum compositions, while Phase II was more specific to chewing gums in line with the invention and included only four chewing gum compositions.

Testing Procedures – Phase I

11. Phase I was designed as a broader-scale evaluation of chewing gums. In Phase I, six chewing gum compositions were prepared and tested for various properties. As set forth in Table 1, the six chewing gum compositions included: (1) a chewing gum composition with

reduced menthol flavoring, citrus flavoring and WS-3; (2) a chewing gum composition with reduced menthol flavoring, berry flavoring and WS-3; (3) a chewing gum composition with a citrus flavoring and no WS-3; (4) a chewing gum composition with a citrus flavoring and WS-3; (5) a chewing gum composition with a berry flavoring and no WS-3; and (6) a chewing gum composition with a berry flavoring and WS-3.

TABLE 1 – Compositions of Samples 1-6

	Sample 1 *Mint, Citrus, WS-3* **(%)**	**Sample 2** *Mint, Berry, WS-3* **(%)**	**Sample 3** *Citrus* **(%)**	**Sample 4** *Citrus, WS-3* **(%)**	**Sample 5** *Berry* **(%)**	**Sample 6** *Berry, WS-3* **(%)**
Gum base	23.91	23.91	27	27	27	27
Bulk Sweeteners	73.94	73.94	63.93	63.93	63.93	63.93
Lecithin	0	0	0.25	0.25	0.25	0.25
Reduced Menthol Mint Flavor*	0.65	0.65	0	0	0	0
Citrus Flavor	0.65	0	1.29	1.2755	0	1.2755
WS-3	0	0	0	0.0155	0	0.0155
Citric Acid	0	0	0.315	.315	0.315	.315
Malic Acid	0	0	0.305	.305	0.305	.305
Berry Flavor	0	0.65	0	0	1.29	0
Glycyrrhizin	0.74	0.74	0	0	0	0
Colorants	0.038	0.038	0.038	0.038	0.038	0.038
Emulsifiers	0	0	0.625	0.625	0.625	0.625
Glycerine	0	0	6.25	6.25	6.25	6.25
Total	**100**	**100**	**100**	**100**	**100**	**100**

* *Reduced Menthol Mint Flavor includes reduced menthol peppermint oil with 2.35% WS-3.*

12. A full panel descriptive analysis was conducted on each of the six samples. Eleven descriptive panelists evaluated various attributes of the chewing gums, including aromatics,

basic tastes, feeling factors, and texture. In addition to qualitative summaries of the products, the panelists were asked to quantify the attributes on a 15-point scale.

13. The samples were presented to the panelists blind, using three-digit codes. Four samples were evaluated per session, with each sample being chewed for a period of ten minutes, with a one minute aftertaste evaluation. The samples were evaluated with two replications.

14. Standard Spectrum™ universal references were used for aromatics, including applesauce, orange juice, and grape juice. Standard basic taste solutions were used, including sweet (sucrose), sour (citric acid), and bitter (artificial caffeine). Internally developed descriptive profiles of Stride™ Sweet Berry, Stride™ Forever Fruit, and Trident™ Original were also used as sensory references. Standard rinsing agents were used, including filtered water and unsalted crackers.

15. Repeated Measures analyses were used to determine significant differences at the 0.05% significance level.

Results of Phase I

Reduced-Menthol Mint Plus Flavor (Samples 1 and 2)

16. Samples 1 and 2, which included a reduced-menthol mint, WS-3, and fruit flavoring, were chewed by the panelists and evaluated. Sample 1 included citrus flavor, and Sample 2 included berry flavor.

17. Panel data showed a high level of off-notes in Samples 1 and 2. The level of off notes in Samples 1 and 2 was significantly greater than the level of off-notes in Samples 3-6 (the samples without the reduced-menthol mint flavor).

18. Qualitatively, Sample 1 was described as having a "complex aromatic profile" with a citrus up front note, followed by a peppermint sensation. The citrus flavor became rindy and less intense over time. The Sample provided a dark, licorice and brown spice impression. The Sample became increasingly bitter and had an offnote, which was described as "soapy, chemical, medicinal, plastic/Band-Aid, turpentine, and metallic."

19. Qualitatively, Sample 2 was described as having first a minty note, followed by a berry note. Various notes were detected, including licorice, cardamom, herbal, root beer, and piney. The offnote was described as chemical-y.

20. Based upon the quantitative and qualitative analysis of Samples 1 and 2, it is likely that these samples would be determined to be unacceptable from a consumer standpoint, and would not provide a beneficial perception to the consumer.

Fruit Flavors (Samples 3-6)

21. In the same sessions as the evaluation of Samples 1-2 described above, Samples 3-6 were evaluated by the panelists for various attributes. Samples 3-6 included chewing gums having (1) citrus flavor without WS-3 [Sample 3], (2) berry flavor without WS-3 [Sample 4], (3) citrus flavor with WS-3 [Sample 5], and (4) berry flavor with WS-3 [Sample 6].

22. Qualitatively, Sample 3 was described as having a citrus fruit taste with no offnotes. Sample 5 was described as very similar to Sample 3, but was "slightly higher in fruit intensity at 1:00, and slightly sweeter later in the chew."

23. Qualitatively, Sample 4 was described as having a mixed berry taste. Sample 6 was described as very similar to Sample 4, but was "slightly higher in mouth sensation later in the chew and slightly lower in fruit intensity earlier in the chew."

24. The fruit intensity levels of the chewing gums at three time periods during the chewing stage were analyzed quantitatively by the panelists. The results are set forth in Table 2 below.

Table 2 - Fruit Intensity Levels of Samples 1-6

Time	Sample 1 Mint, Citrus, WS-3	Sample 2 Mint, Berry, WS-3	Sample 3 Citrus	Sample 4 Citrus, WS-3	Sample 5 Berry	Sample 6 Berry, WS-3
1:00	3.06 d	3.22 d	6.85 ab	6.94 a	6.15 bc	5.90 c
5:00	2.27 b	2.40 b	5.07 a	5.20 a	4.96 a	4.64 a
10:00	1.64 b	1.65 b	4.05 a	4.08 a	3.85 a	3.59 a

25. Based upon the quantitative data set forth in Table 2, it can be determined that the chewing gums where the flavor system included reduced-menthol mint flavor (Samples 1 and 2) resulted in a statistically significant lower level of fruit intensity. In fact, the fruit intensity of the chewing gums having reduced-menthol mint at the 1:00 mark was about 50% of the fruit intensity of the chewing gum samples that did not include the reduced-menthol mint flavor.

26. Thus, based upon the quantitative data for Samples 1 and 2, it can be determined that the combination of reduced-menthol mint, fruit flavor, and WS-3 provides a detrimental effect to the fruit intensity of the chewing gum.

27. Due to the relatively large difference in flavor type and intensity between the chewing gums with the reduced-menthol mint flavor (Samples 1 and 2) and chewing gums without the reduced-menthol mint flavor (Samples 3-6), context effect prevented the panelists from detecting the more subtle differences between the samples with and without WS-3 (Samples

3 vs. 4 and Samples 5 vs. 6). Even though numeric differences in flavor intensity can be seen in Table 2, these differences are not statistically different.

28. Due to the context effect seen from the inclusion of samples with reduced-menthol mint, I was asked to perform a second analysis (Phase II) of Samples 3-6. The second analysis (Phase II) was to be conducted using only Samples 3-6, thus eliminating the context effect seen in Phase I.

Testing Procedures – Phase II (Fruit Flavors With and Without WS-3)

29. To eliminate the context effect seen in Phase I, a second Phase of analysis for chewing gums corresponding to Samples 3-6 was scheduled. Notably, this second phase (Phase II) asked the panelists to analyze chewing gums corresponding to Samples 3-6, separate and apart from Samples 1-2. Without the context effect from Samples 1 and 2, it was believed that the differences between Samples 3-6 would be more detectable.

30. To overcome the context effect of tasting Samples 1-2 along with Samples 3-6 in one test, Phase II involved side-by-side evaluations of chewing gums corresponding to Samples 3-6.

31. For Phase II, the samples were renumbered such that Sample 7 included a chewing gum having citrus flavoring without WS-3. Sample 8 included a chewing gum having a berry flavoring without WS-3. Sample 9 included a chewing gum having a citrus flavoring with WS-3. Finally, Sample 10 included a chewing gum having a berry flavoring with WS-3. The compositions of Samples 7-10 correspond to those of Samples 3-6.

32. A full panel descriptive analysis was conducted on each of the Samples, with two replications in each evaluation. Eight descriptive panelists were asked to evaluate the chewing gums including citrus flavoring (Samples 7 and 9) in a controlled, side by side

environment. Similarly, nine descriptive panelists were asked to evaluate the chewing gums including berry flavoring (Samples 8 and 10) in a controlled, side by side environment. In this fashion, the results for citrus-flavored and berry-flavored chewing gums would not be subjected to the context effect of the reduced-menthol mint-flavored chewing gums. The differences between the citrus and berry flavored gums were not expected to be of a magnitude that would give rise to such context effects.

33. The panelists were asked to evaluate the chewing gum Samples for flavor intensity at various time periods in the chewing stage. In addition to qualitative summaries of the chewing gum Samples, the panelists were asked to quantify the fruit intensity of the chewing gum Samples on a 15-point scale.

34. The Samples were presented to the panelists blind, using three-digit codes. Four Samples were evaluated per session, with each Sample being chewed for a period of ten minutes. The Samples were evaluated with two replications.

35. Standard Spectrum™ universal references were used for aromatics, including applesauce, orange juice, and grape juice. Standard basic taste solutions were used, including sweet (sucrose), sour (citric acid), and bitter (artificial caffeine). Internally developed descriptive profiles of Stride™ Sweet Berry, Stride™ Forever Fruit, and Trident™ Original were also used as sensory references. Standard rinsing agents were used, including filtered water and unsalted crackers.

36. Repeated Measures analyses were used to determine significant differences at the 0.05% and 0.10% significance level.

Results of Phase II

37. Samples 7-10 were chewed by the panelists and evaluated. Sample 7 included citrus flavor, Sample 8 included citrus flavor with WS-3, Sample 9 included berry flavor, and Sample 10 included berry flavor with WS-3.

38. The quantitative Attribute Ratings of Samples 7-8 are set forth in Table 4 below.

Table 4 – Attribute Ratings of Samples 7-8

	Sample 7 (*corresponds to Sample 3*) Citrus	**Sample 8 (*corresponds to Sample 4*) Citrus, WS-3**
Sour	1.09b	1.53a*
Mouth Sensation	1.60b	2.19a**
Chemical Cool	0.73b	1.27a**
Citrus	5.50a	5.65a
Sweet	9.05a	8.79a
Total Impact	8.67a	8.86a

**Significant at the 0.10% significance level*
***Significant at the 0.05% significance level*

39. Quantitatively, the chewing gums including citrus flavor demonstrated a clear difference with and without the inclusion of WS-3. As can be seen, the panel data showed a significant difference between citrus flavored gums with and without WS-3 in several important flavor categories. The panel detected a boost in sour at the 10% significance level and in chemical cool and mouth sensation at the 5% significance level for the sample with WS-3. Taken together, those attributes would imply a flavor boost as flavor is comprised of aromatics, basic tastes, and feeling factors. For each of these attributes, the chewing gum including citrus flavor and WS-3 provided a higher attribute intensity level than that without WS-3.

40. The combination of several attributes was used to determine and evaluate the potential consumer effect that the chewing gum will have. In fact, the attributes of mouth sensation, sour, and chemical cool, in combination, are quite telling with respect to the total flavor experience of the panelist. The fact that these categories experienced significantly higher levels in chewing gums with WS-3 demonstrated a marked improvement in the chewing gum.

41. Qualitatively, the chewing gums including citrus flavor with WS-3 were described as having a citrus note that is "more distinct and clear" than the chewing gums without WS-3. Such qualitative analysis supports the finding that the addition of WS-3 provides an improvement in the citrus-flavored chewing gum.

42. Based upon the significant increase in attributes in citrus flavored chewing gums including WS-3, as well as the qualitative experience of a "more distinct and clear" citrus note, it was determined that chewing gums having citrus flavor in combination with WS-3 will have a beneficial effect on consumers and would therefore be acceptable.

43. The quantitative Attribute Ratings of Samples 9-10 are set forth in Table 5 below.

Table 5 – Attribute Ratings of Samples 9-10

	Sample 9 (*corresponds to Sample 5*) Berry	**Sample 10 (*corresponds to Sample 6*) Berry, WS-3**
Sour	0.85b	1.10a**
Mouth Sensation	1.71b	2.16a**
Chemical Cool	1.31b	1.80a**
Berry	3.84a	3.67a
Sweet	8.52b	8.79a*
Total Impact	7.92a	7.96a

*Significant at the 0.10% significance level
**Significant at the 0.05% significance level

44. Similarly, the chewing gums including berry flavor demonstrated a clear quantitative difference with and without the inclusion of WS-3. As can be seen, the panel data showed a significant difference between berry flavored gums with and without WS-3 in several important flavor categories. The panel detected a boost in sweet at the 10% significance level and in chemical cool, mouth sensation, and sour at the 5% significance level for the sample with WS-3. Taken together, those attributes would imply a flavor boost as flavor is comprised of aromatics, basic tastes, and feeling factors.

45. For each of these categories, the chewing gum including berry flavor and WS-3 provided a higher flavor attribute intensity level than that without WS-3.

46. The combination of several attributes is used to determine and evaluate the potential consumer effect that the chewing gum will have. As with the citrus-flavored chewing gum results set forth above, the combination of the attributes of mouth sensation, sour, sweet, and

chemical cool, in combination, are quite telling with respect to the total flavor experience of the panelist. The fact that these categories experienced significantly higher levels in chewing gums with WS-3 demonstrates a marked improvement in the chewing gum.

47. Based upon the significant increase in attributes in berry flavored chewing gums including WS-3, it was determined that chewing gums having berry flavor in combination with WS-3 will have an improved beneficial effect on consumers and would therefore be acceptable.

CONCLUSIONS

48. Conventionally, it is assumed that the addition of WS-3 would not have an impact as to the flavor impact of a chewing gum. Even further, addition of WS-3 in such minimal amounts would not have been expected to have any demonstrable effect on the flavor intensity levels of chewing gums. However, the tests conducted demonstrate that the addition of WS-3 to fruit flavored chewing gums had a noticeable impact as to the overall flavor intensity of the chewing gum.

49. The comparative tests conducted show that chewing gums incorporating reduced-menthol mint flavoring, fruit flavoring, and WS-3 provided product with levels of off-notes that are statistically significantly higher than chewing gums without reduced-menthol mint flavoring. Such high levels of off-notes would likely result in a chewing gum with an unacceptable taste perception. It is therefore determined that such chewing gum compositions would not have a beneficial effect on consumers and would therefore not be acceptable.

50. The comparative tests conducted show that chewing gum incorporating WS-3 in combination with a citrus flavoring composition provides a statistically significantly higher level of

attributes including sourness, mouth sensation, and chemical cooling. Taken together, these attributes result in a citrus flavored chewing gum with enhanced flavor perception.

51. Similarly, the comparative tests conducted show that chewing gum incorporating WS-3 in combination with a berry flavoring composition provides a statistically significantly higher level of attributes including sourness, mouth sensation, sweetness, and chemical cooling. Taken together, these attributes result in a berry flavored chewing gum with enhanced flavor perception.

52. Based upon my understandings of flavors and consumer analysis, and my knowledge of known scientific principles in the field, it is clear that that the combination of WS-3 in the claimed amounts and a fruit flavoring would provide a product having an enhanced flavor perception.

53. It was previously known that WS-3 provides a cooling effect to mint chewing gum products. However, that WS-3 provides an enhanced fruit flavor perception is highly unexpected and surprising.

I declare the foregoing to be true and accurate to the best of my knowledge under penalty of law.

Dated: 12/23/08

Signed: _____
Maura Titone